

section, the Food and Drug Administration will notify the requester that the Food and Drug Administration is giving the submitter a notice and an opportunity to object. Whenever the Food and Drug Administration sends a notice to a submitter under paragraph (e)(3) of this section, the Food and Drug Administration will notify the requester of this fact.

(f) The notice requirements in paragraph (e) of this section do not apply in the following situations:

(1) The Food and Drug Administration decided not to disclose the records;

(2) The information has previously been published or made generally available;

(3) Disclosure is required by a regulation issued after notice and opportunity for public comment, that specifies narrow categories of records that are to be disclosed under the Freedom of Information Act, but in this case a submitter may still designate records as described in paragraph (d) of this section, and in exceptional cases, the Food and Drug Administration may, at its discretion, follow the notice procedures in paragraph (e) of this section;

(4) The information requested has not been designated by the submitter as exempt from disclosure when the submitter had an opportunity to do so at the time of submission of the information or within a reasonable time thereafter, unless the Food and Drug Administration has substantial reason to believe that disclosure of the information would result in competitive harm; or

(5) The designation appears to be obviously frivolous, but in this case the Food and Drug Administration will still give the submitter the written notice required by paragraph (e)(3) of this section (although this notice need not explain our decision or include a copy of the records), and the Food and Drug Administration will notify the requester as described in paragraph (e)(5) of this section.

[42 FR 15616, Mar. 22, 1977, as amended at 59 FR 535, Jan. 5, 1994]

§ 20.62 Inter- or intra-agency memoranda or letters.

All communications within the Executive Branch of the Federal govern-

ment which are in written form or which are subsequently reduced to writing may be withheld from public disclosure except that factual information which is reasonably segregable in accordance with the rule established in § 20.22 is available for public disclosure.

§ 20.63 Personnel, medical, and similar files, disclosure of which constitutes a clearly unwarranted invasion of personal privacy.

(a) The names or other information which would identify patients or research subjects in any medical or similar report, test, study, or other research project shall be deleted before the record is made available for public disclosure.

(b) The names and other information which would identify patients or research subjects should be deleted from any record before it is submitted to the Food and Drug Administration. If the Food and Drug Administration subsequently needs the names of such individuals, a separate request will be made.

(c) Requests for deletion of business or product names prior to disclosure of any record to the public shall not be granted on the ground of privacy, but such deletion may be justified under another exemption established in this subpart, e.g., the exemption for trade secrets and confidential commercial or financial information under § 20.61.

(d) Names of individuals conducting investigations, studies, or tests on products or ingredients shall not be deleted prior to disclosure of any record to the public unless extraordinary circumstances are shown.

(e) A request for all records relating to a specific individual will be denied as a clearly unwarranted invasion of personal privacy unless accompanied by the written consent of the individual named.

(f) The names and any information that would identify the voluntary reporter or any other person associated with an adverse event involving a human drug, biologic, or medical device product shall not be disclosed by the Food and Drug Administration or by a manufacturer in possession of such reports in response to a request, demand, or order. Information that